



NEW JERSEY
DEPARTMENT OF HEALTH
AND SENIOR SERVICES
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NEW JERSEY STATE SANITARY CODE
CHAPTER 8
COLLECTION, PROCESSING, STORAGE AND
DISTRIBUTION OF BLOOD
N.J.A.C. 8:8-1 et seq.

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CHAPTER TABLE OF CONTENTS

	<u>PAGE</u>		<u>PAGE</u>
SUBCHAPTER 1. GENERAL PROVISIONS		SUBCHAPTER 7. BLOOD AND BLOOD COMPONENTS	
8:8-1.1	Compliance 1	8:8-7.1	General criteria 9-10
8:8-1.2	Definitions..... 1-2	8:8-7.2	Testing 10
8:8-1.3	Licensure 2-3	8:8-7.3	through 8:8-7.14 (Reserved) 10-11
8:8-1.4	Inspection 3	SUBCHAPTER 8. COLLECTION OF BLOOD	
8:8-1.5	Proficiency testing..... 3	8:8-8.1	General criteria 11
8:8-1.6	Brokers 3	8:8-8.2	Donor's emergency care..... 11
8:8-1.7	Exemptions..... 3	8:8-8.3	Medical contingency plan 11
8:8-1.8	Waivers 3	8:8-8.4	Donor protection 11
SUBCHAPTER 2. PERSONNEL		8:8-8.5	Method of blood and blood component collection..... 11-12
8:8-2.1	Blood bank director..... 3-4	8:8-8.6	Pilot samples 12
8:8-2.2	Donor and/or transfusion related personnel 4	8:8-8.7	Blood containers 12
8:8-2.3	Blood bank personnel..... 4	8:8-8.8	Labeling 12
SUBCHAPTER 3. FACILITIES, EQUIPMENT AND CONTAMINATED MATERIAL		8:8-8.9	Sterility testing..... 12
8:8-3.1	Facilities and equipment..... 4	8:8-8.10	Autologous collection/transfusion 12-13
8:8-3.2	Contaminated material 5	8:8-8.11	Directed donation..... 13
SUBCHAPTER 4. MANAGEMENT		8:8-8.12	Perioperative autologous transfusion 13
8:8-4.1	Quality control and quality assurance 5	8:8-8.13	Therapeutic phlebotomy 13-14
8:8-4.2	Procedures 5	8:8-8.14	Routine plasmapheresis 14
8:8-4.3	Documented review..... 5-6	8:8-8.15	Cytapheresis 14
8:8-4.4	Errors and accidents 6	8:8-8.16	Immunized donor 15
SUBCHAPTER 5. RECORDS AND REPORTING REQUIREMENTS		SUBCHAPTER 9. RECIPIENT BLOOD TESTING	
8:8-5.1	Records..... 6-8	8:8-9.1	General provisions 15-16
8:8-5.2	Reporting requirements 8	8:8-9.2	Suspected transfusion reactions 16
8:8-5.3	through 8:8-5.5 (Reserved) 8	8:8-9.3	Operative blood order schedules 16
SUBCHAPTER 6. CRITERIA FOR DONOR SELECTION		8:8-9.4	Urgent requirement for blood 16
8:8-6.1	Donor identification 8	SUBCHAPTER 10. ISSUE AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS FOR TRANSFUSION	
8:8-6.2	Medical history; physical examinations; bleeding limitations..... 8	8:8-10.1	Issue of blood..... 16-17
8:8-6.3	Donor selection 8	8:8-10.2	Administration of blood and blood components 17
8:8-6.4	Information provided to the donor 9	8:8-10.3	Reissue of blood..... 17
8:8-6.5	AIDS Screening requirements..... 9	8:8-10.4	through 8:8-10.7 (Reserved) 17
		SUBCHAPTER 11. STORAGE OF BLOOD	
		8:8-11.1	General provisions 17
		8:8-11.2	Refrigerators for the storage of blood 18

PAGE

8:8-11.3	Freezers for blood components	18
8:8-11.4	Room temperature storage	18
8:8-11.5	Temperature monitoring systems	18
8:8-11.6	Inspection of stored blood	18
8:8-11.7	Expiration dates of blood and blood components	18
8:8-11.8	Packaging and transportation	18

PAGE

**SUBCHAPTER 12. OUT-OF-HOSPITAL
TRANSFUSIONS**

8:8-12.1	General provisions	18-19
8:8-12.2	Out-of-hospital transfusions (OOHT)	19
8:8-12.3	Out-of-hospital transfusions (OOHT) in emergency situations.....	19

CHAPTER 8

COLLECTION, PROCESSING, STORAGE AND DISTRIBUTION OF BLOOD

Authority

N.J.S.A. 26:1A-7 and 26:2A-7.

SUBCHAPTER 1. GENERAL PROVISIONS

8:8-1.1 Compliance

(a) Persons operating blood banks in this State shall meet the qualifications and conduct blood banks in conformity with N.J.S.A. 26:2A-2 et seq. and all rules in this chapter.

(b) Failure to comply with N.J.S.A. 26:2A-2 et seq. and with this chapter shall be cause for revocation of license and imposition of penalties as prescribed by N.J.S.A. 26:2A-2 et seq.

8:8-1.2 Definitions

For the purpose of this chapter, the terms listed below shall be defined and interpreted as follows:

"Accident" means a non-preventable occurrence.

"Additive solution system" means blood preservative systems designed primarily for the extended storage of red blood cells. These systems utilize a second preservative solution for red cell storage in addition to the anticoagulant solution necessary for whole blood collection.

"Autologous donation/transfusion" means the collection of blood and blood components from a donor/recipient for subsequent reinfusion into the same individual.

"Blood bank" means any facility involved in the handling of human blood, blood component or products and which participates in any of the following operations: collection, processing, donor or recipient testing, storage, distribution, and administration of blood and blood components for therapeutic purposes.

"Blood components" means those preparations that are separated from whole blood and are intended for use as final products for therapeutic purposes, for further manufacturing, or as products used for in vitro testing.

"Brokerage" means procuring, selling and distributing of whole blood, components and blood products without engaging in processing, alteration or other manipulation of the blood component.

"Closed system" means a system in which the blood container is not entered or air introduced.

"Code of Federal Regulations" means the current Code of Federal Regulations, as amended and supplemented, Title 21, parts 600 through 640.

"Collection" means the procedure for obtaining blood by donor or recipient phlebotomy.

"Commissioner" means the Commissioner of New Jersey State Department of Health and Senior Services or his or her duly authorized agent.

"Crossing over" means the transfusion of a donation of blood and/or blood components, originally collected for autologous transfusion, to a recipient other than the original donor/recipient.

"Cytapheresis" means the procedure in which blood is removed from the donor, certain cellular elements are separated, and the remaining formed elements and residual plasma are returned to the donor.

"Department" means the New Jersey State Department of Health and Senior Services.

"Designated donor" means a donor that is selected by a recipient for transfusion to this recipient at a later date.

"Directed donation" means the collection of blood or blood components from a designated donor.

"Distribution" means the transfer of blood or blood components from one blood bank facility to any other location for processing or storage or for the purpose of providing the blood for therapeutic, prophylactic or in vitro purposes.

"Donor" means and includes any individual from whom blood or components are collected by a blood bank.

"Error" means a preventable occurrence.

"Health system" means a multidivisional hospital with a blood bank and no more than three satellite blood bank facilities.

"Hemapheresis" means the process of separating freshly drawn whole blood into various blood components and products, some of which are retained while the remainder are reinfused into the donor.

"HIV antigen" means the Human Immunodeficiency Virus antigen.

"HIV-1" means the Human Immunodeficiency Virus type 1.

"HIV-2" means the Human Immunodeficiency Virus type 2.

"Homologous or allogeneic donation" means the collection of blood or blood components for subsequent transfusion to a recipient other than the donor.

"Key person" means individuals designated by the blood bank director.

"Mobile unit" means a moveable, transient unit that is used to collect blood from donors not at the blood bank site.

"Office of Biologics" means the Federal Office of Biologics, Department of Health and Human Services.

"Phlebotomist" means a person who obtains blood from donors by venipuncture.

"Plasmapheresis" means the procedure in which blood is removed from the donor, the plasma is separated from the formed elements and at least the red blood cells are returned to the donor.

"Preparation" means the method used to manufacture blood and blood components.

"Processing" means all tests and procedures required to prepare and identify the blood and blood products as to their suitability for therapeutic, prophylactic or other in vivo or in vitro purposes.

"Pyrogen-free" means a system free from any material capable of causing a febrile response.

"Reagent" means a substance used for any in vitro purpose.

"Recipient" means any person who receives a transfusion of whole blood or blood components.

"Satellite blood bank" means a facility which is part of a health system which does emergency or limited blood banking activities.

"Service" means any of the functions outlined in the Blood Bank License Application form supplied by the Department.

"Significant step" means any step that would be necessary to reconstruct, from the record alone, the procedures performed and who performed them.

"Standards of the American Association of Blood Banks" means the current standards, as amended and supplemented, of the American Association of Blood Banks, National Office, 8101 Glenbrook Rd., Bethesda, MD 20814-2749.

"Storage" means the physical environment of blood or blood components during collection, storage, distribution, transportation or processing.

"Therapeutic phlebotomy" means the removal of whole blood from a donor for the purpose of medical treatment.

8:8-1.3 Licensure

(a) Application for an initial license to conduct a blood bank, as required under the provisions of N.J.S.A. 26:2A-2 et seq., commonly known as the Blood Bank Licensing Act and this chapter, shall be made on forms provided for that purpose by the State of New Jersey.

(b) A blood bank license shall be obtained whenever any function related to the collection, processing, storage, distribution or the administration of blood and blood components is performed.

(c) A separate blood bank license shall be obtained for each permanent location of a blood bank even if the blood bank is owned and operated by another licensed blood bank of the same or different name.

(d) Renewal of the license will be on an annual basis on or before November 10th of each year on forms provided for that purpose by the State of New Jersey.

(e) Amendments to the license shall be as follows:

1. A license renewal shall be obtained 30 days prior to change in the location or the name of the blood bank.

2. The Department shall be notified in writing, 30 days prior to a change, whenever the ownership, corporate structure, director, and/or services of a blood bank change.

(f) The blood bank shall perform only those services, related to this chapter for which they specifically request and receive licensure. In the case of new services, written approval shall be received from the Department prior to initiating the new service.

(g) Blood and blood components for therapeutic purposes shall only be distributed to a New Jersey licensed blood bank unless a nonsurgical situation exists which could not be anticipated and blood and blood components are necessary on an emergency basis to treat a life-threatening situation as specified in N.J.A.C. 8:8-12.3(c).

(h) Pursuant to N.J.S.A. 26:2A-4, the following blood bank licensure fees shall be effective November 1, 1992:

1. Transfusion Services:

Number of Transfusions	Fee
0-1,000	\$200.00
1,001-2,000	300.00
2,001-3,000	400.00
3,001-4,000	500.00
4,001-5,000	600.00
5,001- +	700.00

2. Collection Centers:

Number of Transfusions	Fee
0 - 200	\$ 250.00
201 - 1,500	500.00
1,501 - 3,000	750.00
3,001 - 5,000	1,000.00
5,001 - 10,000	1,250.00
10,001 - 15,000	1,500.00
15,000 - 25,000	1,600.00
25,001 - 35,000	1,700.00
35,001 - 50,000	1,800.00
50,001 - +	1,900.00

3. Other Blood Bank Services:

Type	Fee
Collection Site	\$100.00
Broker	200.00
Industrial Blood Bank	200.00
Home Transfusion Service	200.00

8:8-1.4 Inspection

(a) Blood bank facilities and operations shall be made available for inspection upon request by any authorized representative of the Department during normal working hours.

(b) Reports of inspections of blood banks made by the Office of Biologics may be accepted for purposes of approving and issuing renewal of licenses.

8:8-1.5 Proficiency testing

(a) Blood banks must successfully participate in a proficiency testing program approved by the Department.

(b) Records of all proficiency testing results shall be maintained, including results and interpretations.

(c) Proficiency test results shall be periodically reviewed and evaluated by the blood bank director.

8:8-1.6 Brokers

Brokers shall maintain records, applicable to the Department, of all applicable standards and procedures set forth in this chapter.

8:8-1.7 Exemptions

The Department is empowered to waive such of these regulations as may be necessary for purposes of research, experimentation and new methodologies in blood banking activities, provided requests for such activities, are received in writing and approved by the Department.

8:8-1.8 Waivers

The Public Health Council on the advise of the Commissioner may promulgate, enforce and may amend or repeal these regulations that at any given time shall be no less stringent than the complete interim or revised Code of Federal Regulations in effect at that time. In administering the Blood Bank Licensing Act, the Department can seek the advice and recommendations of an advisory committee.

SUBCHAPTER 2. PERSONNEL

8:8-2.1 Blood bank director

(a) The blood bank director shall administer the blood bank as follows:

1. The director shall be responsible and shall have authority for all procedures and policies relating to all phases of donor and recipient testing as well as the collection, processing, storage, and distribution of all blood and blood components. Procedures and policies for the administration of blood and blood components shall be established in consultation with the blood bank director.

2. The director shall be responsible for compliance with N.J.S.A. 26:2A-2 et seq. and the rules set forth in this chapter.

3. The director shall not individually serve as director or co-director of more than three blood banks, laboratories or one health system. If the blood bank is an integral part of the clinical laboratory, this shall be considered one facility.

4. The director shall spend an adequate amount of time in the blood bank to direct and supervise the technical performance of the staff. The director shall be readily available for personal or telephone consultation.

5. The director shall be responsible for the employment of qualified blood bank personnel, their in-service training and their adherence to established policies and procedures.

6. If the director is to be absent, the director must arrange for a qualified substitute director.

(b) Qualifications of the blood bank director shall be as follows:

1. The blood bank director shall be a physician licensed to practice medicine in the State of New Jersey. The physician requirement shall be waived for industrial manufacturers, brokers and facilities licensed to transfuse in emergency situations only (see N.J.A.C. 8:8-12.3).

2. The blood bank director shall have four years of fulltime experience and/or training appropriate to the services provided by the blood bank, as described in (b)3 below. For new and developing procedures performed by the blood bank, the blood bank director shall have at least two years of experience.

3. Appropriate experience shall include, but shall not be limited to:

- i. Evaluation of donor suitability;
- ii. Donor and recipient testing;
- iii. Blood and blood component collection, preparation, storage, processing and distribution; and
- iv. Administration of blood and blood components for therapeutic purposes.

8:8-2.2 Donor and/or transfusion related personnel

(a) The blood bank shall have one or more supervisors who under the general direction of the blood bank director supervise all functions related to the collection of blood and blood components, and in the absence of the blood bank director are responsible for proper performance of these procedures.

(b) General provisions for donor/transfusion related personnel are:

1. Each blood bank during the collection or transfusion of blood shall have a responsible individual on the premises who, according to N.J.A.C. 8:8-2.2(c), shall be qualified to provide emergency care and in out-of-hospital transfusion situations performs the transfusion.

2. An adequate number of personnel shall be available.

3. All other personnel associated with donor or transfusion related functions shall be suitably trained and supervised in the performance of their prescribed tasks. Donor personnel responsible for determining donor suitability shall demonstrate their familiarity with donor eligibility standards to the satisfaction of the director of the blood bank.

(c) Donor or transfusion emergency care personnel qualifications shall be as follows:

1. A physician licensed in the State or a registered nurse (R.N.) holding a current certificate of registration who has fulfilled the following requirements:

- i. Has taken an eight hour course in cardiopulmonary resuscitation (CPR) for health care providers and holds a current CPR certification.

(d) A phlebotomist shall be properly trained or supervised for six months and be proficient in the collection of blood from a donor.

(e) All other personnel associated with donor related functions must be suitably trained and supervised in the performance of their prescribed tasks.

8:8-2.3 Blood bank personnel

(a) The blood bank shall have one or more supervisors who under the general direction of the blood bank director supervise technical personnel, perform tests requiring special skills, and in the absence of the director shall be responsible for proper performance of all blood bank procedures.

(b) There shall be a sufficient number of properly qualified technical personnel to meet volume and complexity of technical procedures performed by the blood bank.

(c) The blood bank supervisor shall meet the requirements of N.J.A.C. 8:44 or possess a Specialist in Blood Banking (SBB) with two years experience subsequent to graduation. The two years of experience shall be waived if the individual was a blood bank supervisor prior to obtaining the SBB.

SUBCHAPTER 3. FACILITIES, EQUIPMENT AND CONTAMINATED MATERIAL

8:8-3.1 Facilities and equipment

(a) Quarters, environment, and equipment shall be provided to maintain safe and acceptable standards for handling of human blood and blood components.

(b) Blood donor facilities shall consist of at least a waiting room, private screening area for donor questioning, bleeding area, donor recovery area, lavatory facilities and the proper equipment for collection and immediate storage of blood.

(c) The blood bank shall also provide a processing laboratory as follows:

1. The laboratory shall have appropriate equipment for donor and/or recipient testing, component preparation, record keeping, storage and distribution of blood and blood components.

2. All laboratory tests required for proper donor blood processing, not performed by the collecting facility, shall be referred to a laboratory or blood bank licensed by the Department or certified by the Health Care Financing Administration (HCFA), if out-of-State.

8:8-3.2 Contaminated material

Contaminated material shall be disposed in a manner consistent with the rules of the New Jersey Department of Health and Senior Services, Public Health and Environmental Laboratories, and the New Jersey Department of Environmental Protection at N.J.A.C. 7:26-3A.

SUBCHAPTER 4. MANAGEMENT

8:8-4.1 Quality control and quality assurance

(a) All blood banks shall have quality control and quality assurance programs which shall be in compliance with these rules, and shall be sufficiently comprehensive to ensure that blood and blood components, reagents and equipment perform as expected.

(b) The quality control and the quality assurance programs shall include at least the following:

1. Written procedures that include all policies and procedures developed for use;
2. Evidence of validation of methods;
3. Evidence of periodic evaluation of reagents and equipment including the date of performance;
4. Evidence of periodic evaluation of blood and blood components in accordance with, whichever is more stringent, the current Code of Federal Regulations and/or the current Standards of the American Association of Blood Banks;
5. Evidence of periodic evaluation to determine that policies and procedures are appropriate and are followed;
6. Evidence of daily review of computer maintained error correction records by the blood bank director or supervisor.
7. Evidence of appropriate corrective action; and
8. Review by the supervisor or the director.

8:8-4.2 Procedures

(a) All policies and procedures developed for use in the blood bank and required by this chapter shall be detailed in a written procedure manual.

(b) Each procedure shall have a current pertinent literature reference.

(c) The actual test procedures used shall coincide with the manufacturers' current product insert or written documentation from the manufacturer.

(d) The most current edition of the manufacturer's product inserts shall be available.

(e) The procedure manual shall be reviewed by the blood bank director annually and this review shall be documented by date and the blood bank director's signature.

(f) All significant changes to procedures shall be reviewed, dated and signed by the blood bank director.

8:8-4.3 Documented review

(a) When blood or blood components are collected and/or prepared, a key person in the operation of the blood bank shall conduct a documented review prior to the release and final labelling of blood and blood components to ensure that blood from unsuitable donors shall not be distributed for transfusion or further manufacture. If this function is performed by computer, validation of the computer program, as outlined in N.J.A.C. 8:8-5.1(d), shall be performed. This review procedure shall be in writing and the procedure shall include tracking of all collected and/or prepared blood and blood components, to assure that:

1. The sequence of the numbers of the blood and blood components drawn are verified and donor numbers for which no donations are available are accounted for;
2. All required testing, as outlined in N.J.A.C. 8:8-7.2, Testing, is performed on all blood and blood components, with specimens drawn from the donor at the time of collection, before release for transfusion;
3. Blood or blood components with positive or questionable test results are not released for homologous or directed transfusion;
4. Blood or blood components collected from donors that shall be deferred are not released for homologous or directed transfusion or for further manufacture;
5. If required tests are performed by the blood bank, the testing is performed correctly and properly interpreted as determined by at least the following criteria:
 - i. Personnel are following the blood bank's established procedures for the test;
 - ii. Equipment is correctly set-up for test method specific adjustments;
 - iii. Test results on the machine printout can be traced to the worklist;
 - iv. Test runs, that are unacceptable by the criteria specified in the manufacturers' product insert, are repeated;
 - v. Appropriate repeat testing is performed; and

vi. Review of the interpretation of all final test results to assure that the interpretation complies with state requirements, when applicable, or the manufacturers' product insert;

6. If required tests are performed by personnel outside the blood bank, the criteria used to determine a final reactive or nonreactive result coincides with the blood bank's own policy of interpreting results used to discard blood and blood components for transfusion; and

7. That all blood and blood components from donations that have positive or questionable test results are quarantined until their final disposition is determined or they are destroyed.

(b) Final disposition/destruction of records shall be completed at the time of disposition/destruction and documented review shall verify that records accurately reflect that disposition/destruction.

8:8-4.4 Errors and accidents

(a) If an error occurs and any component prepared from a unit improperly tested, not tested, or tested properly but improperly interpreted for ABO or infectious diseases is labeled and released for transfusion, fractionation, reagent production, research or other use, immediate effort shall be made to locate and quarantine all components until satisfactory resolution occurs.

(b) If an accident occurs and any component is released, which is not suitable for transfusion, fractionation, reagent production, research or other use, immediate effort shall be made to locate and destroy all components.

(c) If a whole blood unit or any blood component has been transfused prior to recognition of the error or accident, the medical director of the blood collection facility shall be immediately notified and shall take immediate appropriate action to resolve the problem. If the error or accident has resulted in the transfusion of blood or blood components that could result in infectious disease or other harmful consequences, appropriate medical staff from the collection facility shall notify the patient/recipient's hospital blood bank director who shall document that the patient/recipient's physician is notified of the error or accident and advised that it is his or her responsibility to notify the patient/recipient, or his/her representative, of the error. Thorough and complete documentation shall be made as to these actions.

SUBCHAPTER 5. RECORDS AND REPORTING REQUIREMENTS

8:8-5.1 Records

(a) Suitable legible records prepared with indelible material shall be maintained for a period of not less than five years. Records needed to trace a unit of blood or blood component from its source to final disposition shall be kept for

at least 10 years after transfusion or five years after the latest expiration date for the individual product, but in no case for less than 10 years.

(b) All corrections to errors made in the records shall:

1. Not conceal the original entry;
2. Document the reason for the correction; and
3. Include the date the change was made and the initials of the person making the change.

(c) Worklists or loadlists that list the sequence of specimens tested shall be prepared prior to testing.

(d) Workrecords of tests shall be maintained and these records shall indicate final results together with all corresponding instrument readings and calculations. Where instrumentation produces tracings or printouts of results, these tracings or printouts shall be retained in a readily traceable manner and may serve as the workrecord.

(e) If records are maintained on computer systems, the following apply:

1. Prior to use or when modifications are made to the program, validation of all computer programs, including, but not limited to, those dealing with processing, labeling, and distribution of blood and blood components, shall be required as follows:

- i. To determine if software consistently performs as required and within pre-established limits; and
- ii. To include review of confidentiality of donor information, security of data and system documentation.

2. Adequate provisions shall be made to safeguard against the eventuality of unexpected electronic loss of data from the computer storage medium.

3. A system shall be in existence which maintains duplicate records on electronic storage media, updates these duplicates continuously and/or transfers electronically stored data periodically to hard copy such as prints or microfiche.

4. Written procedures shall be available for describing each of the blood bank's methods for performing requirements in (e)l through 3 above.

5. The computer shall automatically note, at the time of correction, when corrections are made to verified results.

6. The computer record shall maintain the original verified entry, including the date, time and the identity of the person performing the test. When corrections to verified results are made, both the original and corrected

entries shall show the date, time and identity of the person performing the original and corrected records.

7. Records maintained on computer shall comply with all requirements of this chapter.

8. The computer shall list donor collection records by the sequential donor numeric or alphanumeric identifier.

(f) The records shall:

1. Include all data secured and developed by blood banks concerning donor and/or recipient testing, donor identification, medical qualifications, registration as well as the processing, storage and distribution and final disposition of blood and blood components;

2. Make it possible to trace a unit of any blood or blood component by a sequential numeric or alphanumeric identifier from source (donor collection facility) to final disposition (for example transfused, shipped, autoclaved);

3. Be readily available for review;

4. Be made available on forms provided by the Department for the purpose of preparing the State's Statistical Summary of Blood Use report annually by January 31, of each year; and

5. Include the actual result of each test observed, recorded immediately, and the final interpretation recorded upon completion of testing.

(g) Before blood is issued for transfusion, test results for each recipient sample shall be compared with the following:

1. Past records of previous ABO and Rh typing results for the past 12 months; and

2. Past records of all patients known to have significant unexpected antibodies; severe adverse reactions to transfusion, and/or difficulty in blood typing.

(h) If computers are used, an alternate method shall be available and used which allows access to the information required in (g) above in the case of computer failure.

(i) Records shall include at least the following:

1. Donor records:

i. An annual record of each unit of blood and blood component, listed by sequential numeric or alphanumeric identifier, as to its source bank and final disposition;

ii. Donor history, examination, consent, deferral, reactions and also the result of required laboratory tests performed on plasmapheresis and cytapheresis donors;

iii. An annual alphabetical file of donor registration cards or a cross index system;

iv. Blood and component labelling, including initials of person responsible for such labelling;

v. Storage temperatures of components, including dated and initialled temperature recording charts;

vi. Results of visual inspection of blood;

vii. Results of blood processing, including results and interpretation of all tests and retests;

viii. Component preparation, including all relevant dates and times;

ix. Documentation of separation and pooling of recovered plasma;

x. Documentation of units included in pooling of source plasma;

xi. Reissue records, including records of proper temperature maintenance; and

xii. A system that relates a donor with each previous donation.

2. Recipient records shall include:

i. An alphabetical file of the recipient and all units administered;

ii. Each recipient's ABO and Rh type available for immediate reference for at least the past 12 months;

iii. Patients known to have significant unexpected antibodies, adverse reactions to transfusion and/or difficulty in blood grouping and typing available for immediate reference for at least the past five years;

iv. Transfusion request records;

v. Test results, interpretations and release or issue date for compatibility testing;

vi. Emergency release of blood including signature of requesting physician, type of blood and blood component.

3. List of therapeutic bleedings, including signed request by physician, donor's disease and disposition of units;

4. Detailed procedure manual including all policies and procedures developed for use in the blood bank and required by this chapter;

5. Evidence of annual review of the procedure manual by the blood bank director;

6. A data sheet for each cytopheresis procedure and the following information recorded: volume of blood processed; anticoagulants given; duration of procedure; volume of product; drugs given; identity of the donor; any reactions that occurred and how they were treated and any other information necessary to ensure the proper preparation of the component and the safety of the donor.

7. Quality control and quality assurance records, including but not limited to: periodic evaluation of personnel, blood and blood components, reagents, equipment, including dates of performance; test performed; observed results; interpretations; identification of personnel performing the test; any appropriate correction action taken; and review by supervisor and/or director.

8. Antibody identification records;

9. Reports of adverse reactions and laboratory investigation of suspect transfusion reactions;

10. Lot numbers of supplies and reagents.

11. A method to identify persons performing each significant step in collecting, processing, compatibility testing and distributing blood or blood components; and

12. Shipping records from the blood distributor with written documentation that indicates that, at the time of blood and blood component receipt, components listed on the shipping record were verified as received.

8:8-5.2 Reporting requirements

(a) Transfusion reactions shall be reported as follows:

1. Any hemolytic, life threatening or delayed hemolytic transfusion reaction must be reported on forms provided by the Department within 10 days of occurrence.

2. Any fatal transfusion reaction shall be reported by telephone by the next working day of the event, with written follow-up on forms provided by the Department within 10 days of occurrence.

(b) Transfusion associated AIDS shall be reported as follows:

1. Any known or presumed case of transfusion associated AIDS brought to the attention of a blood bank shall be reported to the Department within 10 days on forms provided for this purpose.

2. All prospective donors found to test positive for hepatitis B surface antigen shall be reported to the Department within 10 days on forms provided for this

purpose and shall be considered ineligible for transfusion purposes as long as they continue to be identified on current lists of interdicted donors supplied by the Department.

(c) Errors, as outlined in N.J.A.C. 8:8-4.4(a), that result in the availability of unsuitable blood and blood components for transfusion or distribution, shall be reported on forms provided by the Department within 10 days of the recognition of the error.

(d) Errors that result in the wrong blood or blood component being transfused, regardless of harm to the recipient, shall be reported on forms provided by the Department within 10 days of the recognition of the error.

8:8-5.3 (Reserved)

8:8-5.4 (Reserved)

8:8-5.5 (Reserved)

SUBCHAPTER 6. CRITERIA FOR DONOR SELECTION

8:8-6.1 Donor identification

(a) Blood donors shall be identified by an identification card or another form of authorized identification.

(b) The type of identification used shall be written on the donor registration card at the time of each blood donation.

8:8-6.2 Medical history; physical examinations; bleeding limitations

Medical history, physical examinations, bleeding limitations of the donor shall be consistent with, whichever is more stringent, the most recent Code of Federal Regulations or the most recent Standards of the American Association of Blood Banks. If necessary, these documents may be reviewed at the Department of Health and Senior Services, Clinical Laboratory Improvement Services, Health and Agriculture Building, Room 401, Trenton, New Jersey 08625-0360.

8:8-6.3 Donor selection

(a) On the day of donation the prospective donor's history shall be evaluated and the donor examined by qualified blood bank personnel trained to follow guidelines acceptable to the Department in order to determine that blood donation will not be detrimental to the donor and to determine that the donor has no evidence of disease transmissible by blood transfusion.

(b) Donors shall be excluded from donating blood for transfusion while their names appear in the latest revision of publications supplied to the blood bank by the Department which prohibit them from serving as a donor.

(c) Before blood or blood components are issued for distribution, permanent deferral records, which include reason for deferral for donor past medical history and all tests required in N.J.A.C. 8:8-7.2. Testing shall be reviewed to determine if the blood and blood components meet all the requirements for homologous use. Blood and blood components which do not meet these requirements can not be used for homologous transfusion.

8:8-6.4 Information provided to the donor

(a) Consent shall be obtained in writing from the prospective donor after the procedure has been explained in terms the donor can understand and after the donor has had an opportunity to ask questions and refuse consent. Consent shall include information on significant risks of the procedure and tests performed to reduce the risks of infectious disease to the recipient.

(b) The donor must be instructed in post phlebotomy care and cautioned as to possible adverse reactions.

(c) The blood bank director shall be responsible for a mechanism for notifying the donors of the cause of rejection.

8:8-6.5 AIDS screening requirements

(a) All blood and blood components collected in New Jersey are subject to the requirements of this section.

(b) Educational material must be given to the blood donors prior to the collection of blood which will allow donors to determine whether or not they have engaged in high risk behavior.

(c) All donors including those utilized in hemapheresis, must be screened by history for the early signs and symptoms of AIDS.

(d) The collecting agency shall ensure that all blood and blood components collected in New Jersey, including those obtained by hemapheresis, be screened for HIV-1, HIV-2 and HIV antigen as specified in N.J.A.C. 8:8-7.2. Laboratory tests not performed by the collecting facility shall be referred to a blood bank or laboratory licensed to perform HIV testing by the Department or, if out-of-State, certified by Health Care Financing Administration (HCFA) to perform HIV testing. It shall be the responsibility of the receiving blood bank to assure that any blood brought in from out-of-State sources shall be tested for HIV types 1, 2 and HIV antigen. If the blood is used for homologous transfusion, it shall be tested as all other blood and blood components.

(e) Blood and blood components that are positive, as defined by Centers for Disease Control (CDC) in the "Morbidity and Mortality Weekly Report" of August 14, 1987, in "Laboratory Evidence for or Against HIV Infection," as amended and supplemented, incorporated herein by reference, to serologic tests for HIV types 1, 2 and HIV antigen or collected from a donor known to be positive to serologic tests

for HIV types 1, 2 and HIV antigen shall either be discarded or used for research purposes only.

(f) Prior to a donation of blood or blood component each donor shall be notified in writing and shall have signed a written statement confirming that:

1. The blood or blood components shall be tested for evidence of the probable causative agent of acquired immune deficiency syndrome.

2. Donors found to have serologic evidence of HIV shall be placed on a confidential internal deferral list and may, if deemed appropriate by the Department, a confidential statewide deferral list.

3. The donor shall be notified of the test results in accordance with requirements described in (i) below.

4. Blood or blood components shall not be donated for transfusion purposes by a person if the person has reason to believe that he or she has engaged in high risk behavior.

(g) All blood banks must notify the donor of results when there is serologic evidence of the probable causative agent of AIDS as currently outlined by the Department.

(h) Reactive donors must be notified and counseled in person. Every effort shall be made to accomplish face to face notification and counselling.

(i) Blood banks must maintain records pertaining to all HIV requirements and test results. These records must be kept in a confidential manner.

(j) Testing facilities shall participate in a proficiency program acceptable to the Department.

SUBCHAPTER 7. BLOOD AND BLOOD COMPONENTS

8:8-7.1 General criteria

(a) The procedure for the collection, processing, storage, and distribution of blood and blood components shall meet the requirements of this chapter.

(b) Blood banks shall establish criteria for collection, processing, storage, and distribution, according to current standards, acceptable to the Department.

(c) Sale or exchange of blood and/or blood products positive for HIV and/or HBsAg shall not be made without the express permission, in writing, of the Department.

(d) Blood banks distributing blood and blood components shall:

1. Have available an information circular with each product explaining its proper indications and usage (thawing, dosage, stability, side effects, adverse reactions, hazards, etc.);

2. Provide accurate expiration dates and hours on the container label for all blood and blood components; and

3. Meet licensed expiration dates for the product.

(e) The preparation of all blood and blood components shall be consistent with, whichever is more stringent, the Code of Federal Regulations, as amended or supplemented, or the Standards of American Association of Blood Banks, as amended or supplemented. If necessary, these documents may be reviewed at the Department of Health and Senior Services, Clinical Laboratory Improvement Services, Health and Agriculture Building, Room 401, Trenton, New Jersey 08625-0360.

8:8-7.2 Testing

(a) All laboratory tests shall be made on specimens of blood taken from the donor at the time of phlebotomy in properly identified tubes.

(b) FDA licensed reagents shall be used for screening tests, if they are available.

(c) Required infectious disease testing includes a serologic test for syphilis (STS), Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C Virus (HCV), Hepatitis B Core Antibody (HBcAb), antibody to Human Immunodeficiency Virus Type I (HIV-1), antibody to Human Immunodeficiency Virus Type 2 (HIV-2), Human Immunodeficiency Virus antigen (HIV antigen) and antibody to Human T-Lymphotropic viruses I/II (HTLV 1/11).

(d) Testing shall be performed as required in N.J.A.C. 8:8-4.2 and comply with this chapter.

(e) The blood or blood components shall not be used for therapeutic purposes unless results of test(s) are clearly negative except where delay occasioned by testing may result in serious threat to the health and well-being of the recipient.

(f) In instances where untested units are transfused, the attending physician shall attest in writing to the existence of an emergency and if the test is subsequently positive, the recipient's physician must be notified.

(g) Determination of ABO group:

1. Each container of blood shall be properly identified and labeled as to its blood group.

2. The ABO type of each blood donation shall be determined by testing the red cells of the donor using known Anti-A and Anti-B sera, and by testing the serum or plasma for expected antibodies using known A1 and B red blood cells. The two methods of testing shall be

recorded and be in complete agreement before any label or release can be effected for the unit of blood.

3. All Anti-A and Anti-B sera shall meet the Code of Federal Regulations minimum requirements, and the procedures used shall follow the manufacturer's directions.

4. Previous records of ABO type shall not serve as identification of units, subsequently given by the same donor. New determinations shall be made for each collection.

(h) Determination of D type:

1. The D type of each container of donor blood shall be determined with Anti-D reagent.

2. If the blood is D negative, it shall be tested using a technique designed to detect D^u.

3. Only anti-sera meeting the Code of Federal Regulations minimum requirements for the products shall be used and the technique of typing shall be that recommended by the manufacturer.

(i) Determination of antibodies:

1. Each container of blood shall be tested for unexpected antibodies using a screening cell suspension which meets the Code of Federal Regulations minimum requirements.

2. The techniques employed shall be those which will detect clinically significant antibodies and shall include the anti-human globulin test.

3. Blood in which antibodies are found shall be used in a manner not detrimental to the recipient.

(j) Repeat testing: The facility at which the transfusion is administered must confirm the ABO type, on a sample obtained from the integral attached segment, of all units of whole blood and red blood cells, and the D type of all D negative units of whole blood and red blood cells.

(k) Performance of any additional testing for product quality and patient safety is permitted under this chapter. This testing shall comply with all applicable requirements of this chapter.

8:8-7.3 (Reserved)

8:8-7.4 (Reserved)

8:8-7.5 (Reserved)

8:8-7.6 (Reserved)

8:8-7.7 (Reserved)

8:8-7.8 (Reserved)

8:8-7.9 (Reserved)

8:8-7.10 (Reserved)

8:8-7.11 (Reserved)

8:8-7.12 (Reserved)

8:8-7.13 (Reserved)

8:8-7.14 (Reserved)

3. Emergency vehicle on hand or telephone number of local ambulance squad and/or local police;

4. Name, address and telephone number of physician on call with hours of coverage, or name, address and telephone number of emergency room of nearest hospital;

5. When a private physician is providing medical coverage, personnel will be responsible for:

i. Notifying the physician of the location and telephone number of the facility or recipient's home and the time that the procedure is being initiated;

ii. Reconfirming the hours of coverage;

iii. Notifying the physician at the end of the operation.

(b) When a hospital in the area is providing medical coverage, personnel will be responsible for:

1. Notifying the hospital emergency room of the location and telephone number of the facility and the hour the procedure is being initiated;

2. Notifying the hospital emergency room at the close of operation.

(c) A copy of the Medical contingency plan for each location must be maintained on file on the premises of each licensed blood bank for a period of not less than five years.

8:8-8.4 Donor protection

(a) Preparation of the donor's skin for phlebotomy shall be adequate to afford protection from infection to the donor and to the future recipient.

(b) All equipment used in the collection of blood, such as syringes, needles, lancets or other blood letting devices, capable of transmitting infection to donor or recipient, shall be sterile and pyrogen free.

(c) Disposable thermometers or other temperature checking device maintained in a sanitary manner shall be used.

(d) All personnel concerned with the collection of blood shall be instructed in appropriate first aid procedures in the event of donor reaction.

(e) Suitable drugs, supplies and instructions for use shall be immediately available at all times.

8:8-8.5 Method of blood and blood component collection

(a) Immediately prior to collection of the blood or blood component, a unique sequential numeric or alphanumeric identification shall be placed on all material related to that

SUBCHAPTER 8. COLLECTION OF BLOOD

8:8-8.1 General criteria

(a) Blood banks wishing to employ the techniques set forth in this subchapter shall file their protocol and a request in writing to the Department, prior to initiation of this service.

(b) The techniques set forth in this subchapter can be employed upon receipt of written approval from the Department.

8:8-8.2 Donor's emergency care

(a) Blood shall be drawn from donors only when a physician or donor emergency care personnel are available on the premises.

(b) The qualifications of donor emergency care personnel and the procedures for implementation of donor selection and donor care standards shall be approved by the Department.

(c) This rule shall not waive the requirements for physicians' attendance at a location where plasmapheresis is being performed in an opened system.

(d) If home transfusions are performed, a second responsible person shall be available on the premises to help with emergency situations.

8:8-8.3 Medical contingency plan

(a) Each location for collection of whole blood units or the transfusion of blood and blood components shall have a current medical contingency plan specific for that location which shall include:

1. Name, address and telephone number of nearest hospital;

2. Route of evacuation to that hospital;

donation, such as the blood component label, the donor medical history record and pilot tubes. This number shall identify all material related to the particular blood donation.

(b) The method employed for the removal of blood from the donor must conform to accepted standards of asepsis.

(c) Blood containers and donor sets shall be sterile and pyrogen-free.

(d) A closed system must be used except for blood cell separation instruments that use an open system.

(e) If more than one venipuncture is needed, another set and container must be used.

(f) The container into which the blood is collected at one venipuncture shall be the final container.

(g) During bleeding, the anticoagulant solution and the blood shall be thoroughly mixed.

(h) The outside of the container shall be kept clean.

(i) Immediately after bleeding, the blood shall be placed in storage at 1-6°C, unless platelets are to be harvested.

8:8-8.6 Pilot samples

(a) At the time of collection the integral donor tubing must be filled with anticoagulated blood and sealed in such a manner that it will be available for subsequent tests for serologic compatibility.

(b) The integral donor tubing segments must be separable from the container without breaking the sterility of the container.

(c) At the time of collection additional blood may be collected for laboratory tests provided containers are properly labelled before or at the time of collection, accompany the blood container, and are reidentified with the blood container after filling.

8:8-8.7 Blood containers

(a) Containers for whole blood and blood components used by licensed establishments, shall be identified by recording the manufacturer's lot numbers and shall be sterile and pyrogen-free.

(b) The containers shall be sufficiently colorless and transparent to permit visual inspection of blood.

(c) They shall be provided with closures which maintain a hermetic seal and prevent contamination of the contents.

(d) The container and the closure shall not interact with the contents under customary conditions of storage and use.

(e) The anticoagulant solution and additive solution systems shall be sterile, pyrogen-free in the amount prescribed

for the volume of blood collected, and prepared according to the Code of Federal Regulations.

8:8-8.8 Labeling

(a) Labeling shall be consistent with the most recent Code of Federal Regulations.

(b) Blood and blood components shall be labelled to include conspicuous notation of incomplete testing and when applicable positive or abnormal test results.

(c) Untested autologous blood collected from a donor/recipient, who has been tested in the last 30 days, shall not be labeled according to standards for uniform labeling of homologous blood. It shall be labeled as follows:

1. With a statement that the blood was collected from a donor known to be tested for FDA-required tests; and

2. The date that the donor recipient was tested.

8:8-8.9 Sterility testing

(a) Sterility testing shall be performed at regular intervals and not less than once monthly, where blood is collected or prepared in an open system. Such tests shall not be done on blood intended for transfusion.

(b) Culture techniques shall be in accordance with the most recent Code of Federal Regulations.

(c) Permanent records of sterility tests, with evidence that the tests have been performed according to the most recent Code of Federal Regulations, and the results shall be kept.

8:8-8.10 Autologous collection/transfusion

(a) Blood banks wishing to employ the techniques set forth in this section shall file their protocol and a request in writing to the Department, prior to initiation of the service.

(b) The techniques set forth in this section can be employed upon receipt of written approval from the Department.

(c) Autologous collection/transfusion shall be done only at the written request of the donor-recipient's physician. A telephone request shall be followed by written confirmation within seven calendar days.

(d) Testing and labelling requirements for autologous donations shall be consistent with, whichever is more stringent, this chapter or the Code of Federal Regulations.

(e) Donor processing for autologous transfusion shall be as follows:

1. Donor qualifications for autologous transfusion may vary from standard donor criteria but this entire procedure must be arranged by consultation between the blood bank director and the donor-patient's physician.

2. If the patient-donor and/or donated unit do not meet the criteria for donor selection listed in this Chapter to protect the recipient, the unit must be labeled "For Autologous Use Only", segregated, and used solely for this purpose.

3. "Crossing over" shall not be allowed.

4. Blood and blood components that test positive or abnormal and are transfused to the donor/recipient shall be labelled with a Biohazard label.

(f) Criteria for donation shall be as follows:

1. Volume of blood must comply with the Code of Federal Regulations.

2. There are no age limits for autologous transfusion procedures.

3. The hemoglobin concentration of patient-donor shall be no less than 11 gms. per dl. The packed cell volume, if substituted, shall be no less than 33 percent.

4. Frequency of phlebotomy for autologous transfusion shall be determined by competent medical decision but blood should not be collected from the patient within 72 hours of the anticipated procedure,

5. Phlebotomy concurrent with transfusion of previously collected autologous units should not be undertaken more frequently than once every three days.

(g) Pretransfusion testing of blood and blood components for autologous transfusion shall be subject to the following:

1. ABO group must be determined by the collection facility. If the transfusion facility is different from the collecting facility, the ABO type must be confirmed.

2. Other factors tested for routine transfusion are optional.

3. Compatibility testing is optional.

(h) If "Autologous Use Only" blood is drawn, all satellite bags shall be labeled "Autologous Use Only" immediately prior to or at the time of the collection.

(i) Crossmatched autologous units that are tested can be stored on the same shelf with the crossmatched homologous and/or directed units for the same recipient.

8:8-8.11 Directed donation

(a) Blood banks wishing to employ the techniques set forth in this section shall file their protocol and a request in writing to the Department, prior to initiating the procedure.

(b) Such techniques can not be employed until written approval is received from the Department.

(c) All requirements of this chapter related to homologous donations shall be followed.

(d) Directed donations shall be initiated only at the written request of the intended recipient's physician or a transfusion facility. A telephone request shall be followed by written confirmation within seven calendar days.

8:8-8.12 Perioperative autologous transfusion

(a) Facilities initiating the perioperative autologous transfusion procedure shall notify the Department in writing within 30 days.

(b) Standards of the American Association of Blood Banks related to perioperative procedures, as amended or supplemented, shall be followed.

8:8-8.13 Therapeutic phlebotomy

(a) General criteria for therapeutic phlebotomy are as follows:

1. Therapeutic phlebotomy shall be done only at the written request of the patient's physician.

2. Any blood or blood component withdrawn from a patient for therapeutic purposes shall be clearly indicated as such on the blood label.

3. The use of this blood or blood component for allogeneic transfusion purposes shall be determined by the physician in charge of the blood bank, in consultation with the recipient's attending physician.

4. Collection of such blood for transfusion purposes shall be restricted to an institution where the status of both the donor and the recipient are known.

5. The unit shall be labeled to indicate the donor's disease.

(b) There shall be a written procedure describing the technique used.

(c) Records shall be maintained which include patient identification, diagnosis, therapeutic procedure, volume of plasma and cells removed, volume replaced, nature of the replacement fluids, any adverse actions, and a record of the administered medications.

(d) Informed written consent of the patient must be obtained.

(e) There shall be provisions for the management of reactions.

(f) If therapeutic phlebotomy procedures and recordkeeping are not entirely performed by blood bank personnel, there shall be a written agreement that specifies the division of responsibilities for assuring compliance with this chapter.

8:8-8.14 Routine plasmapheresis

(a) Blood banks wishing to employ these techniques shall file a request in writing with the Department, including their protocol and other relevant details, prior to initiation of the procedure.

(b) Such techniques may be employed upon receipt of written approval from the Department.

(c) The procedures used shall meet with the approval of the Department and shall include as a minimum the following requirements:

1. Within one week prior to the first plasmapheresis, the donor shall be examined and certified to be in good health by a licensed physician.

2. A licensed physician on the premises shall supervise the performance of these procedures, including the reinfusion of red cells. This requirement may be waived for plasmapheresis procedures using a closed system subject to the following conditions:

i. A request for a waiver shall be submitted in writing to, and approved by, the Department;

ii. N.J.A.C. 8:8-8.2, Donor's emergency care, shall be strictly followed;

iii. Donor emergency care personnel, as required under N.J.A.C. 8:8-2.2(c), shall be on the premises; and

iv. A contingency plan to assure that a physician is available for emergency purposes during the procedure shall be in use. The physician response time shall be no longer than 15 minutes.

3. Prior to each procedure, records shall be made and maintained of the major pertinent elements of each donor's physical condition and must also include a determination of the donor's total protein.

4. A donor shall not serve as a source of plasma unless his or her total protein is within normal limits.

5. Quality control records of the total protein determinations shall be maintained.

6. If a second plasmapheresis is to be performed within 30 days of the first procedure, laboratory tests shall be done on samples of the donor's serum to determine that the protein level and ratio of the various protein components, as shown by electrophoresis, fall within normal limits.

7. A donor shall not serve as a source of plasma while there is any significant change in his health, or in the values of these initial determinations.

8. Periodic determinations shall be made as frequently as necessary and at least every four months to monitor these evaluations.

9. The amount of plasma withdrawn shall be consistent with the current Code of Federal Regulations.

10. Red blood cell loss should not exceed 25 ml per week during serial plasmapheresis.

11. A plasmapheresis donor may donate a unit of whole blood if 48 hours have lapsed since the last plasmapheresis, but at least eight weeks shall elapse after a regular whole blood donation before starting a donor in a plasmapheresis program.

12. A plasmapheresis donor must, on each occasion of plasmapheresis satisfy all requirements of donor whole blood outlined in N.J.A.C. 8:8-6 Criteria for Donor Selection.

8:8-8.15 Cytapheresis

(a) Blood banks wishing to employ these techniques shall file their protocol and a request in writing with the Department, prior to initiation of the procedure.

(b) Such techniques may be employed upon receipt of written approval from the Department.

(c) The procedures used shall meet with the approval of the Department and shall comply with all requirements of this chapter.

(d) A licensed physician on the premises shall supervise the performance of these procedures including the reinfusion procedure. This requirement may be waived for cytappheresis procedures using a closed system subject to the following conditions:

1. A request for a waiver shall be submitted in writing and approved by the Department;

2. N.J.A.C. 8:8-8.2, Donor's emergency care, shall be strictly followed;

3. Donor emergency care personnel, as required under N.J.A.C. 8:8-2.2 (c), shall be on the premises; and

4. A contingency plan to assure that a physician is available for emergency purposes during the procedure shall be in use. The physician response time shall be no longer than 15 minutes.

(e) The interval between procedures shall be at least 48 hours, and no more than 1,000 ml of plasma should be removed per seven days, or 250 ml of red blood cells per eight weeks.

(f) Plasmapheresis requirements as outlined in N.J.S.A. 8:8-7.11 shall apply to donors undergoing cytappheresis at least biweekly over several months.

1. The results of these tests shall be reviewed by a licensed physician to determine suitability for continued donation.

2. The donor must be tested appropriately to detect developing cytopenia.

(g) If a cytappheresis donor donates a unit of whole blood or if it becomes technically impossible to return the donor's red blood cells, at least eight weeks must elapse before a subsequent cytappheresis procedure.

(h) Donors may receive drugs before or during leukapheresis.

1. Such drugs shall not be used for donors whose medical history suggests that they may exacerbate previous intercurrent disease.

2. The blood bank director is responsible for setting appropriate written guidelines in such circumstances.

8:8-8.16 Immunized donor

(a) If specific immunization of a donor is to be performed, the selection and scheduling of the injection of the antigen, and the evaluation of each donor's clinical response, shall be by a qualified physician.

(b) Any material used for immunization shall be either a product licensed under Section 351 of the Public Health Service Act for such purpose or one specifically approved by the Director, Office of Biologics.

(c) Immunization procedures shall be on file at each plasmapheresis center where immunizations are performed.

(d) Each donor to be immunized shall be instructed regarding possible hazards associated with use of his blood at other blood banks and each shall agree that he will not donate blood elsewhere without first divulging his immunization status.

(e) Informed consent of the donor must be obtained.

SUBCHAPTER 9. RECIPIENT BLOOD TESTING

8:8-9.1 General provisions

(a) The requirements in this section shall apply to both hospital and out-of-hospital transfusion of blood for therapeutic purposes.

(b) Forms and request for blood and blood components and forms accompanying recipient blood samples must have sufficient information for the positive identification of the recipient.

(c) The recipient's first and last names and a traceable identification number are required. If more than one identification number is needed to establish the positive identification of the recipient, all the numbers shall be documented on all blood bank documents used for recipient testing.

(d) Incomplete or illegible forms shall not be accepted.

(e) The intended recipient and the blood sample shall be identified at the time of collection by a mechanism which positively identifies the recipient.

(f) The sample for compatibility testing shall be:

1. Identified by a label firmly attached to the sample before leaving the side of the recipient;

2. Labeled at the time of the collection with at least the recipient's first and last names, traceable identification number, the identity of the person drawing the sample and the date the sample was drawn;

3. Obtained within three days of the scheduled transfusion when the recipient has been transfused or pregnant in the preceding three months or this information is not known; and

4. Examined by a qualified person, before a specimen is used for typing or compatibility testing, to confirm that all information on the request form is in agreement with that on the specimen label. In the case of a discrepancy or doubt, another specimen shall be obtained and used for these procedures.

(g) Testing of the recipient's blood shall include at least the following:

1. Determination of ABO type:

i. ABO typing shall be performed on each sample of recipient blood as in N.J.A.C. 8:8-7.2.

ii. Serum tests for Anti-A and Anti-B in neonatal patients should be omitted.

2. D typing:

i. It is sufficient to test each blood sample from the recipient with Anti-D typing sera only.

ii. This will determine whether the recipient should receive D positive or D negative blood.

iii. The test for D^u is unnecessary when testing recipient red cells.

iv. To avoid incorrect designation of a D-negative recipient as D-positive, a control system appropriate to the D reagent in use is required.

3. Detection of unexpected antibodies:

i. Each blood sample submitted with a request for transfusion shall be tested prior to, or concurrently with, the performance of compatibility testing.

ii. Methods for testing for unexpected antibodies shall be those which demonstrate clinically significant antibodies and shall include an antiglobulin test.

4. Compatibility testing:

i. Compatibility testing requirements shall be consistent with the most recent Code of Federal Regulations and shall include a method to verify the ABO group of the donor unit and the recipient.

5. A control system using red blood cells sensitized with IgG shall be used with each negative antiglobulin test.

8:8-9.2 Suspected transfusion reactions

Each blood bank and transfusion service shall have a system for detecting and evaluating suspected adverse reactions to transfusion in accordance with current Standards of the American Association of Blood Banks. All suspected transfusion reactions shall be evaluated promptly.

8:8-9.3 Operative blood order schedules

(a) If type and screen procedure is used, there must be prompt availability of ABO compatible blood to meet unexpected transfusion requirements.

(b) If this blood is needed before compatibility testing is completed, an immediate spin crossmatch must be performed before the blood can be released.

1. Testing should be completed promptly and the results documented.

8:8-9.4 Urgent requirement for blood

(a) Urgent requirements for blood are situations in which delay in provision of blood may unduly jeopardize the patient,

therefore, blood may be issued before completion of routine tests.

(b) The following standards shall apply to urgent situations:

1. Recipients whose ABO and D types have been determined by the transfusing facility without reliance on previous records may receive type-specific blood before required tests have been completed.

2. Recipients whose ABO type is not known shall receive type 0 red blood cells.

3. The record shall contain a statement of the requesting physician indicating that the clinical situation was sufficiently urgent to require release of blood before completion of required testing and the requesting physician's signature.

4. The tag or label shall indicate in a conspicuous fashion that required testing had not been completed at the time of issue.

5. Required tests should be completed promptly.

6. The identification number required in N.J.A.C. 8:8-9.1 and N.J.A.C. 8:8-10.1 shall be traceable.

SUBCHAPTER 10. ISSUE AND ADMINISTRATION OF BLOOD AND BLOOD COMPONENTS FOR TRANSFUSION

8:8-10.1 Issue of blood

(a) A blood transfusion request form indicating the recipient's name, traceable identification number, and ABO and D types shall be completed for each unit of donor blood or component.

(b) A label or tag with the appropriate information to identify the unit with the intended recipient shall be attached to the blood container before its release from the laboratory for transfusion.

(c) At the time the blood or blood component is released from the blood bank for transfusion, the person receiving the blood shall present a written request with sufficient information for the positive identification of the recipient. The technologist who issues the blood shall perform an identification check along with the person picking up the blood. This identification check shall involve active participation by both individuals in a review of the identifying information on the blood bag and the requisition slip. At a minimum the recipient's first and last names, traceable identification number, the type of component requested, and the date of transfusion shall be required. The blood bank shall write the unit number and the type of component issued on the request slip.

(d) Retention of blood samples shall be as follows:

1. A stoppered or sealed sample of each donor blood, and a similar sample of the recipient's blood, shall be stored at 1 to 6°C for at least seven days after transfusion.

8:8-10.2 Administration of blood and blood components

(a) Identification of the recipient and the blood container shall be as follows:

1. Each transfusion service must have a written procedure for the positive identification of the recipient and the blood container.

2. At the bedside, immediately prior to transfusion, two qualified individuals (whose qualifications are determined and verified by the medical institution or the transfusing facility in consultation with the blood bank director) shall simultaneously check and match all information identifying the container with the identifying information on the person of the intended recipient and the compatibility testing request slip. If the information does not match, the initiation of transfusion shall be suspended until the discrepancy is adequately investigated and resolved.

3. At the bedside, immediately after the identifying information in N.J.A.C. 8:8-10.2(a)2. is matched, and before the transfusion is initiated, the two qualified individuals that checked this information shall sign the transfusion form to attest that this information was checked and that it matched.

4. All identification attached to the container shall remain attached at least until the transfusion has been completed.

(b) Blood transfusions shall be conducted as follows:

1. Blood and components shall be transfused through a sterile, pyrogen-free transfusion set equipped with a filter.

2. Warming of blood shall be performed as follows:

i. When warming of blood is performed, it should be accomplished during its passage through the transfusion set.

3. Irradiation of blood shall be consistent with current acceptable standards of the American Association of Blood Banks or current guidelines issued by the Food and Drug Administration, whichever is more stringent.

8:8-10.3 Reissue of blood

(a) Blood or blood components which have been returned to the blood bank shall not be reissued for use unless the following conditions have been met:

1. The container closure or seal has not been punctured or tampered with;

2. The blood has been continuously stored and shipped under controlled conditions, which maintain acceptable temperatures for the product, or it is returned to the blood bank within a pre-determined time, set by the blood bank, which is acceptable to the Department;

3. Original identification labels and tags are attached and unaltered;

4. The original pilot sample has not been removed or tampered with;

5. If applicable, the blood has been allowed to settle long enough to permit reinspection of the plasma; and

6. The records indicate the blood was reissued with documentation of the time it was returned and reissued.

8:8-10.4 (Reserved)

8:8-10.5 (Reserved)

8:8-10.6 (Reserved)

8:8-10.7 (Reserved)

SUBCHAPTER 11. STORAGE OF BLOOD

8:8-11.1 General provisions

(a) The equipment used for the storage of blood shall be kept clean and individual compartments used only for the storage of blood and blood components, blood banking sera, pilot and patient samples.

(b) No food or potentially contaminated material shall be stored in the refrigeration equipment.

(c) Written procedures shall be readily available containing directions on how to maintain blood and blood components within permissible temperatures and including instructions to be followed in the event of power failure or other disruption of refrigeration.

8:8-11.2 Refrigerators for the storage of blood

(a) The refrigerator for the storage of blood shall maintain the blood at a temperature between 1-6°C.

(b) Refrigerators for blood or blood component storage shall be provided with a fan for circulating air or be of a design to ensure that the proper temperature is maintained throughout.

(c) Liquid temperature shall be monitored.

(d) The liquid medium used shall reflect the actual temperature of blood in Storage.

8:8-11.3 Freezers for blood components

(a) Freezers for blood components stored frozen shall maintain the blood component at a temperature below – 18°C.

(b) Liquid nitrogen freezers used to store red blood cells shall maintain them at a gas phase temperature below – 120°C.

8:8-11.4 Room temperature storage

Components for room temperature storage shall be maintained at a temperature of 20 to 24°C.

8:8-11.5 Temperature monitoring systems

(a) All refrigerated equipment used to store blood and blood components shall have a system to record temperature continuously.

(b) The temperature recording device shall be calibrated periodically, inspected at least daily and written records of the temperatures shall be kept on file.

(c) Alarms shall be attached to the refrigeration equipment and shall be subject to the following:

1. Visual and audible alarm systems shall be attached to the equipment to indicate whenever the temperature is outside acceptable ranges.

2. Alarms should be installed in locations to provide 24 hour coverage by night personnel or switchboard operators.

3. The alarms shall be set to activate at a temperature which will allow proper action to be taken before the blood or blood components reach undesirable temperatures.

(d) There shall be a written procedure posted prominently for staff to follow in case of electrical or equipment failure.

8:8-11.6 Inspection of stored blood

(a) Stored blood shall be inspected daily and records maintained during the entire period of storage and immediately prior to issue or use.

(b) If the color or physical appearance is abnormal or there is any indication or suspicion of contamination, the unit of blood shall not be issued for transfusion purposes.

8:8-11.7 Expiration dates of blood and blood components

(a) The expiration date is the last day on which the blood and blood components are considered suitable for transfusion purposes.

(b) Expiration dates shall be in accord with the Code of Federal Regulations, as amended or supplemented.

8:8-11.8 Packaging and transportation

(a) Processed whole blood, modified whole blood and all liquid red blood cell components shall be transported in a manner that will maintain temperatures of one to 10 degrees Centigrade.

(b) Components ordinarily stored at 20 to 24 degrees Centigrade shall be transported at this temperature.

(c) Components ordinarily stored frozen shall be transported in a manner designed to keep them frozen.

(d) Immediately upon arrival, the receiving facility shall transfer the blood to temperature controlled equipment for further storage.

SUBCHAPTER 12. OUT-OF-HOSPITAL TRANSFUSIONS

8:8-12.1 General provisions

(a) Any facility that issues blood and blood components to an Out-of-Hospital Transfusion (OOHT) service shall be a blood bank licensed in accordance with this chapter to perform "Transfusion Services" and "Processing (Routine)".

(b) The OOHT service and the New Jersey licensed "Transfusion Service" shall have a written agreement that specifies the division of responsibilities for assuring compliance with this chapter. If the OOHT service performs no function other than transfusion of the blood, the New Jersey licensed transfusion service shall agree in this written document to perform recipient testing required in N.J.A.C. 8:8-9.1 and N.J.A.C. 8:8-9.2, and to provide technical consultation when necessary.

(c) Blood banks wishing to employ the techniques set forth in this subchapter shall file their protocol and a request in writing with the Department, prior to initiation of the procedure.

(d) Such techniques may be employed upon receipt of written approval from the Department.

(e) The procedures used shall be acceptable to the Department and ensure that there is compliance with this Chapter.

8:8-12.2 Out-of-hospital transfusions (OOHT)

(a) Out-of-hospital transfusions (OOHT) shall be done under medical supervision, and the patient shall be observed during the transfusion and for an appropriate time thereafter for suspected adverse reactions. Specific instructions concerning possible adverse reactions shall be provided in writing for the patient.

(b) Blood or blood components for transfusion shall be prescribed by a physician.

(c) OOHT services shall be licensed to transfuse blood and blood components, in accordance with this chapter.

(d) Recipient safety shall be assured by at least the following:

1. If a physician is not present, the transfusionist shall be a person able to administer emergency care and shall be a registered nurse (R.N.) holding a current certificate of registration who has fulfilled the following requirements:

- i. Has taken an eight hour course in cardiopulmonary resuscitation within three years and successfully passed a practical and written exam on the subject matter.

2. A second responsible person shall be available on the premises to help with emergency situations and to provide the second check required in N.J.A.C. 8:8-10.2.

3. Adherence to N.J.A.C. 8:8-8.3, Medical contingency plan.

(e) The procedures used shall comply with N.J.A.C. 8:8-4, Management, N.J.A.C. 8:8-5, Records and Reporting Requirements, N.J.A.C. 8:8-10.2, Administration of blood and blood components, and N.J.A.C. 8:8-11.1, 8:8-11.4 and 11.8, Storage of blood.

(f) Blood banks functioning only as OOHT services shall also comply with N.J.A.C. 8:8-2, Personnel, N.J.A.C. 8:8-3.2, Contaminated material, N.J.A.C. 8:8-7.1(a), (b) and (d), Blood and blood components, and N.J.A.C. 8:8-9.1, Recipient blood testing.

8:8-12.3 Out-of-hospital transfusions (OOHT) in emergency situations

(a) Facilities not routinely using blood and blood components for therapeutic purposes that can anticipate that they may use them on an emergency basis to treat a life-threatening situation, shall be licensed as outlined in N.J.A.C. 8:8-1.3, Licensure.

(b) The facilities described in (a) above shall comply with N.J.A.C. 8:8-5, Records and Reporting Requirements, N.J.A.C. 8:8-9, Recipient Blood Testing and N.J.A.C. 8:8-10.1, Administration of blood and blood components.

(c) If a nonsurgical situation exists, which could not be anticipated and blood or blood components for therapeutic purposes are necessary on an emergency basis to treat a life-threatening situation, a licensed blood bank shall be permitted to release blood and blood components to an entity not licensed as a blood bank provided that:

1. The attending physician shall attest in writing to the existence of the emergency and the licensed blood bank shall maintain this documentation as required in 8:8-5.1, Records.

2. N.J.A.C. 8:8-9, Recipient Blood Testing and N.J.A.C. 8:8-10.1, Administration of blood and blood components are followed.